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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,574	04/06/2001	Salvatore Albani	UCSD1310-1	6601

7590 05/18/2004

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,574	ALBANI ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,33,34,38-42 and 60-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24, 33-34, 38-42, 60-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 1, 2004 has been entered. Accordingly, claims 1-24, 33-34, 38-42, and 60-66 remain pending in the instant application.

All grounds of rejection in the previous Office Action are withdrawn in view of Applicants amendment.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-19, 21, 24, 33-39, 60-62 and 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderton et al.

The claims are directed to an isolated HLS pan DR-binding peptide comprising a stress protein fragment that binds to a MHC class II molecule, wherein the fragment is up to about 30 amino acid residues in length and comprises a core sequence flanked at either end by at least one amino acid, wherein the core sequence has an amino acid sequence selected from the group consisting of SEQ ID NO: 18, 19, 20, 21, 22 and 23, and wherein the fragment comprises a naturally occurring amino acid sequence.

Anderton et al (WO 95/25744) disclose of peptide fragments which are useful for protection against or treatment of an inflammatory disease, including autoimmune diseases, such as diabetes, arthritic diseases, artherosclerosis, multiple sclerosis, myasthenia gravis, or inflammatory responses due to tumor or transplant rejection. Anderton et al further disclose of the production of a fragment identical to SEQ ID NO: 19 of the instant invention. (See Table I and claims).

In view that Anderton et al disclose of a peptide which is 100% identical to the peptide as claimed, the disclosure of Anderton et al is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-24, 33-34, 38-42, and 60-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderton in view of Srivastava, Russel-Jones et al and Guichard et al.

Applicants assert that the rejection has been overcome in view that the claims no longer recite SEQ ID NO: 14 and 15. Applicants further assert that the sequences in the claims of the invention are derived from M. tuberculosis are SEQ ID NO: 6 & 8, found at positions 210-224 and 241-270 of SEQ ID NO: 1, respectively, and that Anderton et al does not disclose of peptides in this range.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be persuasive in view of the teachings of Anderton et al.

Applicants assert that the rejection has been overcome in view that the claims no longer recite SEQ ID NO: 14 and 15. However, as set forth above, the claims still encompass the teachings of Anderton et al, specifically SEQ ID NO: 19 is fully disclosed in Table II of Anderton et al and was used as an immunogen.

Applicants further assert that the sequences in the claims of the invention are derived from M. tuberculosis are SEQ ID NO: 6 & 8, found at positions 210-224 and 503-517 of SEQ ID NO: 1, respectively, and that Anderton et al does not disclose of peptides in this range. However, Applicants are again directed to Table I of Anderton et

al in which a peptide identical to SEQ ID NO: 19 was used as an immunogen. Furthermore, Applicants are directed to Table II, in which immunizing peptides corresponding to positions 211-225 and 506-520 (of SEQ ID NO: 1) were also employed, and found to elicit a response after hsp65 immunization. Consequently, Anderton et al teach of the same immunogenic epitopes recognized by Applicants.

The teachings of Anderton et al are set forth above.

Anderton et al do not teach of the peptide having one or more D-amino acids, covalently linked to an adjuvant, or of a composition comprising an interferon.

Srivastava (US Patent Number 6,455,503) teach of stress protein-peptide complexes containing a therapeutically effective amount of a cytokine including IL-1, IL-2, etc. Srivastava further sets forth that the cytotoxic T cell response may be enhanced by the presence of the cytokine. (See column 7 and claims).

Russel-Jones et al (US Patent Number 5,928,644) teach of covalent attachement of BSA to a peptide antigen results in a significant enhancement of the immune response. (See columns 2-3).

Guichard et al (Proc. Natl. Acad. Sci. USA, Vol. 91, October 1994, pp 9765-9769) teach that the use of D amino acids to replace natural L-peptides results in peptides with a higher metabolic stability, since most natural proteases cannot cleave D-amino acid residues.

Given that 1) Anderton et al have taught of fragments of stress proteins which are identical to the instantly claimed fragments (i.e., SEQ ID NO: 19), and that 2)

Srivastava teaches of the desirability to incorporate cytokines with stress proteins, and that 3) Russel-Jones teaches that covalent attachment of BSA to a peptide results in significant enhancement of the immune response, and that 4) Guichard et al has taught that incorporation of D-amino acids into a peptide results in peptides with a higher metabolic stability, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have incorporated the cytokine with the stress protein as taught by Srivastava, or to the fuse the antigen to BSA as taught by Russel-Jones et al, or to have incorporated a D-amino acid in the peptide antigen as taught by Guichard et al. One would have been motivated to incorporate these changes in view of the advantageous properties displayed by the combination (i.e., increase CTL response, increased immune response, and increased stability), as set forth by Srivastava and Russel-Jones et al and Guichard et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
May 13, 2004